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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
02/07/99, 478	05/15/98	ALVAREZ	V 1101-220

020583

HM12/0619

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EXAMINER

DAVENPORT, A

ART UNIT

PAPER NUMBER

1653

DATE MAILED:

06/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/079,678

Applicant(s)

ALVAREZ ET AL.

Examiner

Avis M. Davenport

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-39, 75, and 98-108 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 75 is/are allowed.
- 6) ☒ Claim(s) 31-39 is/are rejected.
- 7) ☒ Claim(s) 98-108 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Response to Amendment

Claims 31-39, 75, and 98-108 are pending in the instant application.

Claims 31-33 have been amended, claims 1-30, 40-74 and 76-97 have been canceled and claims 98-108 have been added as requested by applicants in the communication filed March 28, 2001.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 31, 32 and 75 under 35 USC §112, second paragraph as lacking antecedent basis is withdrawn. The rejection is withdrawn in view of applicants amendments as set forth in the communication filed March 28, 2001.

The objection of claims 33-39 as being dependent on a rejected base claim is withdrawn. The rejection is withdrawn in view of applicants amendments as set forth in the communication filed March 28, 2001.

Art Unit: 1653

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 31-39 are rejected under 35 U.S.C. 102(e) as being anticipated by O'Mahony.

The reference teaches peptides and proteins that facilitate the transport of an active agent through human or animal tissue. The reference teaches bound peptides and protein or libraries. See the Summary of the invention set forth in column 2 starting at line 11. The peptides or proteins of the invention facilitate the delivery of drugs or agents across human or animal tissue including the GIT or gastro-intestinal tract. The reference anticipates the instant invention claims which are drawn to methods of delivering an active agent *in vivo* by administering a composition comprising a protein which

Art Unit: 1653

specifically binds a GIT receptor wherein the protein is bound to an active agent or drug. The reference reads on the instant invention peptides or proteins because there is no limiting characteristics of the instant invention proteins as claimed except that it bind to a GIT receptor specifically. There is no structure, size, activity or other characteristics set forth to distinguish the instant invention proteins from the prior art proteins. The prior art proteins are not excluded from the instant invention and are therefore anticipatory.

Claims 106-108 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits. While the claims use the term "or" , the proper language should state, " ... any one of claims or

Claims 98-105 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 75 is in condition for allowance.

Art Unit: 1653

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Avis M. Davenport whose telephone number is (703) 308-4002. The examiner can normally be reached on T-F(10:00-8:00) Mondays off.

Art Unit: 1653

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Avis M. Davenport
Primary Examiner
Art Unit 1653

amd

June 17, 2001